Electronic Prescribing of Controlled Substances --- A New Option

Despite multiple articles within the literature regarding the many benefits of electric prescribing (eRx), and the implementation of an eRx incentive program within Medicare that began in 2009, the number of physician practices employing this technology remains limited. A recent study estimated that by the end of 2009 only 25% of all office-based prescribers were using this technology. One road-block to fuller implementation has been the Drug Enforcement Administration’s (DEA) prohibition against the electronic transmission of prescriptions for controlled substances—thus requiring the burden of separate workflows for the prescribing of controlled and non-controlled substance prescriptions. On March 31, the DEA released an interim final rule that will effectively remove this limitation. The following series of frequently-asked–questions (FAQs) addresses important issues related to the availability of this new option to electronically transmit controlled substance prescriptions.

Why were controlled substances prohibited from being electronically transmitted up to now?

The DEA believed that controlled substances carried a much higher risk of diversion and there was a need for increased safeguards from their misuse and abuse in comparison to non-controlled medications. This increased risk relates to the addictive nature of these drugs and the high prices these substances can be sold for on the illegal marketplace. The DEA wanted to develop and implement a more secure process for these substances before allowing their electronic transmission.

Is this the first time the DEA has attempted to address this issue?

No. The DEA released a proposed rule addressing this issue in June, 2008. The procedures defined in that rule were viewed as too burdensome and inflexible by most stakeholders—including the College. The current interim rule, while effectively addressing the diversion issue and facilitating the prosecution of violators, is more responsive to physician burden and workflow issues than the original proposed rule.

When does the new rule take effect?

The new rule takes effect as of June 1, 2010. Since this rule is an interim final rule that also requests further comments from multiple stakeholders, it is likely that there will be further modifications to the rule later in the year.

Is it mandatory to begin electronically transmitting controlled substance prescriptions on June 1?

No. This rule only provides an option for providers to use eRx for controlled substances. Physicians can still choose to write and manually sign the written prescriptions, or alternate as necessary between manually writing or electrically transmitting these prescriptions.
Can I use my current eRx system to transmit controlled substance prescriptions?

An eRx system, whether free-standing or part of an electronic medical record (EHR), must comply with a set of requirements specified in the rule. It is the responsibility of the application provider, your vendor, to hire a qualified third party or approved certification body to audit the system and issue a report on whether the system meets DEA requirements. You will need to contact your vendor to determine if your system meets the DEA requirements.

Do I need any special credentials in addition to my DEA number to engage in eRx of controlled substances?

Yes, “identity proofing” is part of the safeguard procedures used by the DEA. Individual physicians will be required to apply to entities that serve as Federal approved credential service providers (CSPs) or certification authorities (CAs) to verify their identity and obtain the necessary credentials to engage in the eRx of controlled substances. These private organizations already exist to conduct identity proofing and issue identity credentials as part of their existing businesses—contact your eRx vendor to obtain a list of the approved entities in your area. This process can be done in-person or through a remote process. Institutional physicians will have the option to conduct in-person identity proofing in-house.

What are the additional security steps required to transmit a controlled substance eRx?

The DEA is requiring a “two-factor” credential for a physician to approve and sign a controlled substance eRx. A DEA approved eRx system must allow the physician to use two of the following to approve and sign a controlled substance prescription—something you know (e.g. a password); something you have (e.g. a hard token such as a smart card that is stored separate from the computer), and something you are (e.g. biometric information such as a thumb print). In addition, a person in the practice other than that physician must be responsible for checking that the physician has valid credentials to practice medicine, prescribe controlled substances, and engage in the eRx of controlled substances. Once validated, this second person sets the eRx system controls of the practice to allow the physician system access—this is a onetime process called a “logical access control” requirement.

Where can I obtain additional information regarding the eRx of controlled substances?

The DEA provides helpful material regarding this rule on its website at http://www.deadiversion.usdoj.gov/. In addition, the College provides useful information regarding the general topic of eRx, including the eRx of controlled substances, at http://www.acponline.org/running_practice/technology/#eprescribing.